

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 07/21/08 is acknowledged.

Claims 12-13 remain cancelled. Claims **1-11 and 14-15** are pending in this application and claims **1-11 and 14-15** will be examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 , 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "medium or high". The terms: medium and high in claim1 is a relative term, this renders the claim indefinite. The terms medium and high are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Examiner suggests reciting specific values or range.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 10-11 and 14-15 rejected under 35 U.S.C. 102 (b) as being anticipated by Suzuki ET al. (JP 6-094912).

Suzuki discloses that alpha- cyclodextrin and the composition with alpha – cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of **hypertriglycemia**, arteriosclerosis and triglyceride accumulative fatty liver (page 6, paragraph2).

Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40%

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(Examples 1-5 and page 7 of the translation); the alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP 6-094912) in view of Mayer Davis (Diabetes care volume 24, April 2001) and Van Laere et al. (US PG pub 2003/0113310 A1) and Raben et al. (Am. Journal Nutrition 1997; 66; 304-314).

Suzuki discloses that alpha- cyclodextrin and the composition with alpha – cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of **hypertriglycemia**, arteriosclerosis and triglyceride

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acuumulative fatty liver (page 6, paragraph2).

Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4).

Mayer-Davis teaches that lifestyle changes can result in improved glucose tolerance among individuals at high risk for developing type 2 diabetes. **A reduced-fat** diet may result in sustained improvements in **glycemic status** after 5 years. [First Paragraph].

Van Laere et al. teach method for the treatment of obesity, overweight and fluctuations in blood insulin and/or glucose levels (title). Van Laere discloses by referring to US patent 4,396,602 a method of lowering the blood glucose level in mammals. The method comprises administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides. The blood glucose level-lowering agent comprises the enzyme capable of synthesizing sparingly-digestible polysaccharides or oligosaccharides from easily-digestible saccharides, such as monosaccharides, oligosaccharides and polysaccharides. Enzymes providing the above effect are dextranucrase and cyclodextrin-synthesizing enzymes. (see paragraph[0005] on page 1). It is therefore apparent that cyclodextrin helps in lowering

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of blood glucose since the cyclodextrin synthesizing hormones help in lowering the blood glucose level.

Raben et al. teach beneficial effect of beta-cyclodextrin on glucose metabolism and appetite suppression (title). The reference teaches that lower insulin and gastric inhibitory polypeptide response and higher fullness ratings were observed after the meal with beta-cyclodextrin (see abstract). The reference teaches effect of modification and processing procedures of starch on human physiology (especially glycemic and insulinemic responses) (see column 2, first paragraph). The reference also discloses that the resistant starch may reduce the plasma glucose concentration and satiety after ingestion (see column 2, paragraph 2, and last lines.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify food having a glycemic index by reducing the glycemic index of the food comprising alpha-cyclodextrin and administering the same to an individual or individuals with impaired glucose tolerance because Suzuki teaches weight gain inhibitory effects due to alpha-cyclodextrin and its relationship in reducing glucose concentration, Mayer teaches that reduced fat diet may result in improvements in glycemic status and Van Laere teaches a method of administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides by the help of cyclodextrin synthesizing hormones (which indirectly proves that cyclodextrin helps in synthesizing sparingly-digestible saccharides from easily-digestible saccharides) and Raben teaches beneficial effect of beta cyclodextrin on glucose metabolism and appetite suppression. One would have been motivated to try alpha

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cyclodextrin in order to achieve better glucose metabolism with an expectation of obtaining similar results based on the guidance provided by Raben et al. and the combined teachings of the cited references.

With regards to various concentration/amounts, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

8. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over Augustine et al. (European Journal of Clinical Nutrition (2002) 56, 1049-1071) in view of JP 4011865) and further in view of: Raben et al. (Am. Journal Nutrition 1997; 66; 304-314).

Augustine et al. discloses that the glycemic index ranks foods based on their postprandial blood glucose response. Hyperinsulinemia and insulin resistance as well as determinants (e.g. high energy intake, obesity and lack of physical activity have been implicated in the etiology of diabetes. Low glycemic index foods characterized by slowly absorbed carbohydrates have been shown to produce beneficial effect on glucose control, hyperinsulinemia, blood lipids satiety.

JP teaches liquid food additive inhibit glucose absorption treat diabetes obesity comprising extract gymnema leaf cyclodextrin (title). The extract shows sweet taste inhibiting activity and sugar absorption inhibiting activity (see abstract).

Raben et al. teach beneficial effect of beta-cyclodextrin on glucose metabolism and appetite suppression (title). The reference teaches that lower insulin and gastric inhibitory polypeptide response and higher fullness ratings were observed after the meal with beta-cyclodextrin (see abstract).

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to utilize alpha cyclodextrin in foods and lower the glycemic index since JP teaches cyclodextrin possess sugar absorption inhibitory activity and Raben teaches cyclodextrin in lower insulin response.

One skilled in the art would have been motivated to incorporate alpha-cyclodextrin because Augustine teaches that low glycemic index foods characterized by slowly absorbed carbohydrates have been shown to produce beneficial effect on glucose control, hyperinsulinemia, blood lipids satiety. Further motivated by the JP's teachings, that Gymnema cyclodextrin leaf extract shows sugar absorption inhibiting activity, one skilled in the art would have modified food by reducing the glycemic index by combining the food with alpha-cyclodextrin with a reasonable expectation of success. One would have been further motivated to prepare a food product comprising alpha-cyclodextrin for the consumption of humans suffering from diabetes because JP reference teaches that alphacyclodextrin helps in inhibiting glucose absorption and Raben teaches low insulin response with food comprising beta cyclodextrin.

The invention as a whole would thus have been obvious in view of the cited references to one of ordinary skilled in the art at the time the invention was made. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

9. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over Akira et al. (JP57146713) in view of Raben et al. (Am. Journal Nutrition 1997; 66; 304-314).

Akira et al. teach a hypoglycemic that contains saccharides selected from hard-digestive polysaccharides, Oligosaccharides and their derivatives as active ingredients as being used as preventive agents for metabolic diseases. The diseases being characterized as hyperglycemic and arteriosclerosis caused by readily digestive saccarides (see abstarct).

The teachings of Raben et al. have been discussed above. Raben teaches hard digestive saccharide such as cyclodextrin which are resistant starch and may reduce plasma glucose concentration. As such it would have been obvious to one of ordinary

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skilled in the art at the time the invention was made to utilize alpha cyclodextrin in reducing glycemic index of a food. Based on the guidance provided by Raben et al. one would have been motivated to utilize hard digesting saccharide such as alpha cyclodextrin with an expectation of obtaining reduction in glycemic index with a reasonable expectation of success.

Response to Arguments

10. Applicant's arguments with respect to claims 1-11 and 14-15 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612